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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/066,960 | 02/04/2002 | Ross Rabin | NEX83/D | 5849 |

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| EXAMINER | |
|---|---|
| BOWMAN, AMY HUDSON | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | |

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/066,960 | RABIN ET AL. | |
| | Examiner | Art Unit | |
| | Amy H Bowman | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-28 and 32-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/4/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's election without traverse of Group V, claims 29-31, in the reply filed on 10/27/2004 is acknowledged. Claims 1-28 and 32-44 are withdrawn from consideration.

### *Priority*

This application is a division of 09/364,539 with an effective date of 7/29/99. Application 09/364,539 is a continuation in part of application 09/502,344. The instant application does not receive benefit of 09/502,344 because 09/502,344 discloses the method but does disclose the instantly claimed target, c-met.

### *IDS*

Reference AAC on PTO form 1449 filed on 2/4/2002 has not been considered because the reference was not supplied.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being obvious over Gold et al. (U.S. patent 5,270,163), in view of Bottaro et al., further in view of Faletto et al.,

further in view of Toothman et al. (U.S. patent 5,731,424), Jayasena et al. (U.S. patent 5,734,034), or Pagratis et al. (U.S. patent 5,837,834).

Gold et al. has both a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Instant claim 29 is drawn to a method for the isolation of nucleic acid ligands to c-met comprising preparing a candidate mixture of nucleic acids, contacting the mixture with c-met, partitioning the increased affinity nucleic acids from the remainder of the candidate mixture, and amplifying the increased affinity nucleic acids to yield a mixture

of nucleic acids with increased affinity to c-met so that a nucleic acid ligand to c-met may be identified. Claim 30 specifies that the candidate mixture comprise single-stranded nucleic acids. Claim 31 specifies that the single stranded nucleic acids of claim 30 comprise ribonucleic acids.

Gold et al. teach a method for identifying nucleic acid ligands of a target compound from a candidate mixture comprised of single stranded nucleic acids each having a region of randomized sequence. The method comprises contacting the candidate mixture with the target, wherein nucleic acids having increased affinity may be partitioned from the remainder of the candidate mixture, partitioning the increased affinity nucleic acids from the remainder of the candidate mixture, and amplifying the increased affinity nucleic acids to yield a mixture of nucleic acids with increased affinity to the target so that a nucleic acid ligand to the target may be identified (claim 1).

Gold et al. do not teach the method for identifying nucleic acid ligands specific to c-met.

Bottaro et al. teach that the HGF receptor has been identified as the product of the c-met proto-oncogene and that ligands are yet to be identified to c-met. Bottaro et al. further teach that c-met is activated in some tumor cell lines and that there is a need to explore the role of this ligand-receptor system in normal and disease states (see entire document).

Faletto et al. teach a method for obtaining purified HGF and teach antibodies and peptides which bind to HGF and inhibit HGF from binding to its receptor (see entire document).

Toothman et al., Jayasena et al., and Pagratis et al. each teach making nucleic acid ligands to a specific protein, TGF-B, hKGF and elastase, respectively, using the general method taught by Gold et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method taught by Gold et al. to identify nucleic acid ligands to c-met. One of ordinary skill in the art would have been motivated to use the method taught by Gold et al. to identify nucleic acid ligands to c-met because Bottaro et al. teach that c-met is the HGF receptor and is activated in some tumor cell lines, and because Faletto et al. teach that compounds which bind HGF and inhibit its interaction with its receptor can prevent tumor metastasis. One of ordinary skill in the art would have expected the method taught by Gold et al. to be applicable to identify nucleic acid ligands to c-met because Gold et al. state that their method "is generally applicable to make a nucleic acid ligand for any desired target" (column 5, lines 32-34) and further provides for proteins which normally do not bind nucleic acids (see examples 4 and 5 and columns 31 and 32), like HGF. Further, many examples exist in the prior art, exemplified by Toothman et al., Jayasena et al., and Pagratis et al., wherein the method taught by Gold et al. has been used successfully to identify nucleic acid ligands, including RNA ligands which interfere with a receptor interaction (see abstract of Toothman et al. and Pagratis et al.), to a wide variety of proteins, including other growth factors. Therefore, at the time the invention was made, it would have been obvious to one of ordinary skill in the art to use the method of isolating nucleic acid ligands to c-met as claimed.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-31 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,270,163 in view of Faletto et al. and Bottaro et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods claimed in the instant case are a specific version of the general method claimed in Patent '163. Patent '163 and the instant application have a common inventor and assignee.

Instant claim 29 is drawn to a method for the isolation of nucleic acid ligands to c-met comprising preparing a candidate mixture of nucleic acids, contacting the mixture with c-met, partitioning the increased affinity nucleic acids from the remainder of the candidate mixture, and amplifying the increased affinity nucleic acids to yield a mixture of nucleic acids with increased affinity to c-met so that a nucleic acid ligand to c-met

may be identified. Claim 30 specifies that the candidate mixture comprise single-stranded nucleic acids. Claim 31 specifies that the single stranded nucleic acids of claim 30 comprise ribonucleic acids.

Claims 29-31 in the instant application are drawn essentially to the same method as that of claim 1 of Patent '163. The instant method is applied specifically to identifying nucleic acid ligands to c-met, whereas claim 1 of Patent '163 is drawn to the general method for any target.

Faletto et al. teach a method to obtain purified HGF and inhibit the interaction of HGF with its receptor, via antibodies and peptides.

Bottaro et al. teach that the HGF receptor has been identified as the product of the c-met proto-oncogene and that ligands are yet to be identified to c-met. Bottaro et al. further teach that c-met is activated in some tumor cell lines and that there is a need to explore the role of this ligand-receptor system in normal and disease states.

Although the method in claim 1 of Patent '163 and the methods of instant claims 29-31 are not the same, they are not patentably distinct because the method in the instant case is a specific application of the patented method. It would have been obvious to utilize the method of Patent '163 to isolate nucleic acid ligands to c-met because the patented method would have applied to any target, including c-met. One of ordinary skill in the art would have been motivated to find nucleic acid ligands to c-met, the receptor of HGF, because of its known role in tumor cell lines as taught by Bottaro et al. Further, Faletto et al. teach antibodies and peptides which bind HGF and inhibit its interaction with its receptor, and that inhibiting the interaction of HGF and its

receptor will prevent tumor metastasis. Because the protein and its receptor were known in the art and that it was known that it would be useful to identify compounds that bind to the protein or its receptor because of their role in tumor metastasis, it would have been obvious to one of ordinary skill in the art to utilize the patented method for the specific target recited in the instant case.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:30 am – 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Examiner
Art Unit 1635